

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

ANGELA F. ROLA and STANLEY M.
ROLA,

Plaintiffs,

v.

ALLEGIANCE CORPORATION,
BAXTER INTERNATIONAL, INC.
BAXTER HEALTHCARE, S.A., a/k/a
ALLEGIANCE HEALTHCARE Sdn., Bhd.,
MICROFLEX MEDICAL CORP., SATARI
CORPORATION, MCKESSON GENERAL
MEDICAL CORPORATION, SAFESKIN
CORPORATION, BECTON, DICKINSON
& COMPANY n/k/a MAXXIM MEDICAL,
INC., TYCO HEALTHCARE GROUP LP,
LIG, INC. n/k/a SSL AMERICAS, INC.,
JOHNSON & JOHNSON INC., JOHNSON
& JOHNSON MEDICAL, TILLOTSON
HEALTHCARE CORPORATION,
BERGEN BRUNSWICK MEDICAL
CORP. a/k/a DURR MEDICAL CORP.,
CYPRESS MEDICAL PRODUCTS, INC.,
and JOHN DOES 1-100,

Defendants.

MDL Docket 1148

Civil Action No. 01-3017

Judge Edmund Ludwig

**ANSWER AND JURY DEMAND
OF DEFENDANT BECTON,
DICKINSON AND COMPANY**

[W.D.N.Y. Case No. 01-CV-0213]

Becton, Dickinson and Company ("BD"), sometimes incorrectly referred to in the Complaint as Becton, Dickinson & Company, n/k/a Maxxim Medical, Inc., by and through its counsel and for its Answer to Plaintiffs' Complaint, states the following:

PARTIES

1. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint, and therefore, can neither admit nor deny said allegations.

2. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint, and therefore, can neither admit nor deny said allegations.

3. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 3 of the Complaint, and therefore, can neither admit nor deny said allegations.

4. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint, and therefore, can neither admit nor deny said allegations.

5. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint, and therefore, can neither admit nor deny said allegations.

6. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 6 of the Complaint, and therefore, can neither admit nor deny said allegations.

7. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of the Complaint, and therefore, can neither admit nor deny said allegations.

8. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 8 of the Complaint, and therefore, can neither admit nor deny said allegations.

9. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint regarding Maxxim Medical Inc.'s state of incorporation or means of service, and therefore, can neither admit nor deny said

allegations. The remaining allegations contained in paragraph 9 of the Complaint constitute a legal conclusion to which no response is required. To the extent a response is required, BD denies the remaining allegations contained in paragraph 9 of the Complaint.

10. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint, and therefore, can neither admit nor deny said allegations.

11. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 11 of the Complaint, and therefore, can neither admit nor deny said allegations.

12. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 12 of the Complaint, and therefore, can neither admit nor deny said allegations.

13. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 13 of the Complaint, and therefore, can neither admit nor deny said allegations.

14. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the Complaint, and therefore, can neither admit nor deny said allegations.

15. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 15 of the Complaint, and therefore, can neither admit nor deny said allegations.

16. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 16 of the Complaint, and therefore, can neither admit nor deny said allegations.

17. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 17 of the Complaint, and therefore, can neither admit nor deny said allegations.

18. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 18 of the Complaint, and therefore, can neither admit nor deny said allegations.

19. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 19 of the Complaint, and therefore, can neither admit nor deny said allegations.

JURISDICTION AND VENUE

20. BD denies the allegations contained in paragraph 20 of the Complaint.

21. BD denies the allegations contained in paragraph 21 of the Complaint.

THE PRODUCT

22. To the extent that the allegations set forth in paragraph 22 of the Complaint are directed to defendant BD, defendant admits that, at certain times, it manufactured, distributed and/or sold certain latex gloves to the healthcare industry but denies all other allegations directed to it. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of the Complaint to the extent that they refer to other Defendants and, therefore, cannot admit nor deny said allegations.

ALLEGATIONS COMMON TO ALL COUNTS

23. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the Complaint, and therefore, can neither admit nor deny said allegations.

24. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24 of the Complaint, and therefore, can neither admit nor deny said allegations.

25. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25 of the Complaint, and therefore, can neither admit nor deny said allegations.

26. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26 of the Complaint, and therefore, can neither admit nor deny said allegations.

27. To the extent that the allegations set forth in paragraph 27 of the Complaint are directed to Defendant BD, Defendant admits that, at certain times, it manufactured, distributed and/or sold certain latex gloves to the healthcare industry but denies all other allegations directed to it. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 27 to the extent that they relate to other Defendants, and therefore, can neither admit nor deny said allegations.

28. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 28 of the Complaint, and therefore, can neither admit nor deny said allegations.

29. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 29 of the Complaint, and therefore, can neither admit nor deny said allegations.

30. To the extent that the allegations set forth in paragraph 30 of the Complaint are directed to Defendant BD, Defendant denies the allegations contained in paragraph 30 of the Complaint. BD is without knowledge or information sufficient to form a belief as to the truth of

the allegations contained in paragraph 30 of the Complaint to the extent that they relate to other Defendants, and therefore, can neither admit nor deny said allegations.

31. To the extent that the allegations set forth in paragraph 31 of the Complaint are directed to Defendant BD, Defendant denies the allegations contained in paragraph 31 of the Complaint. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 31 of the Complaint to the extent that they relate to other Defendants, and therefore, can neither admit nor deny said allegations.

32. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 32 of the Complaint, and therefore, can neither admit nor deny said allegations.

33. To the extent that the allegations set forth in paragraph 33 of the Complaint are directed to Defendant BD, Defendant denies the allegations contained in paragraph 33 of the Complaint. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 33 of the Complaint to the extent that they relate to other Defendants, and therefore, can neither admit nor deny said allegations.

BACKGROUND FACTS CONCERNING KNOWLEDGE OF LATEX ALLERGY IN THE MEDICAL SUPPLY INDUSTRY

34. To the extent that paragraph 34 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 34 of the Complaint.

35. To the extent that paragraph 35 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 35 of the Complaint.

36. To the extent that paragraph 36 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 36 of the Complaint.

37. To the extent that paragraph 37 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 37 of the Complaint.

38. To the extent that paragraph 38 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 38 of the Complaint.

39. To the extent that paragraph 39 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 39 of the Complaint.

40. To the extent that paragraph 42 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 42 of the Complaint.

41. To the extent that paragraph 41 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 41 of the Complaint.

42. To the extent that paragraph 42 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 42 of the Complaint.

43. To the extent that paragraph 43 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 43 of the Complaint.

44. To the extent that paragraph 44 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 44 of the Complaint.

45. To the extent that paragraph 45 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 45 of the Complaint.

46. To the extent that paragraph 46 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 46 of the Complaint.

47. To the extent that paragraph 47 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 47 of the Complaint.

48. To the extent that paragraph 48 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 48 of the Complaint.

49. To the extent that paragraph 49 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 49 of the Complaint.

50. To the extent that paragraph 50 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 50 of the Complaint.

51. To the extent that paragraph 51 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 51 of the Complaint.

52. To the extent that paragraph 52 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 52 of the Complaint.

53. To the extent that paragraph 53 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 53 of the Complaint.

54. To the extent that paragraph 54 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 54 of the Complaint.

55. To the extent that paragraph 55 of the Complaint purports to characterize specific documents, or statements, such documents or statements speak for themselves and, accordingly BD neither admits nor denies the allegations relating thereto. BD denies all other allegations contained in paragraph 55 of the Complaint.

56. BD denies the allegations of paragraph 56 of the Complaint.

57. BD denies the allegations of paragraph 57 of the Complaint.

58. BD denies the allegations of paragraph 58 of the Complaint.

**COUNT ONE
STRICT LIABILITY**

59. BD incorporates its responses to the allegations contained in paragraphs 1 through 58 of the Complaint as if fully set forth herein.

60. BD denies the allegations contained in paragraph 60 of the Complaint.

61. BD denies the allegations contained in paragraph 61 of the Complaint.

62. BD denies the allegations contained in paragraph 62 of the Complaint.

63. BD denies the allegations contained in paragraph 63 of the Complaint.

64. BD denies the allegations contained in paragraph 64 of the Complaint.

65. BD denies the allegations contained in paragraph 65 of the Complaint.

**COUNT TWO
NEGLIGENCE**

66. BD incorporates its responses to the allegations contained in paragraphs 1 through 65 of the Complaint as if fully set forth herein.

67. BD denies the allegations contained in paragraph 67 of the Complaint.

68. BD denies the allegations contained in paragraph 68 of the Complaint.

**COUNT THREE
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS**

69. BD incorporates its responses to the allegations contained in paragraphs 1 through 68 of the Complaint as if fully set forth herein.

70. BD denies the allegations contained in paragraph 70 of the Complaint.

71. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 71 of the Complaint relating to “Baxter,” and therefore, can neither admit nor deny said allegations. BD denies the remaining allegations contained in paragraph 71.

**COUNT FOUR
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

72. BD incorporates its responses to the allegations contained in paragraphs 1 through 71 of the Complaint as if fully set forth herein.

73. BD denies the allegations contained in paragraph 73 of the Complaint.

74. BD denies the allegations contained in paragraph 74 of the Complaint.

COUNT FIVE
WILLFUL MISREPRESENTATION OF MATERIAL FACTS

75. BD incorporates its responses to the allegations contained in paragraphs 1 through 74 of the Complaint as if fully set forth herein.

76. BD denies the allegations contained in paragraph 76 of the Complaint.

77. BD denies the allegations contained in paragraph 77 of the Complaint.

78. BD denies the allegations contained in paragraph 78 of the Complaint.

79. BD denies the allegations contained in paragraph 79 of the Complaint.

80. BD denies the allegations contained in paragraph 80 of the Complaint.

COUNT SIX
NEGLIGENT MISREPRESENTATION

81. BD incorporates its responses to the allegations contained in paragraphs 1 through 80 of the Complaint as if fully set forth herein.

82. BD denies the allegations contained in paragraph 82 of the Complaint.

83. BD denies the allegations contained in paragraph 83 of the Complaint.

84. BD denies the allegations contained in paragraph 84 of the Complaint.

85. BD denies the allegations contained in paragraph 85 of the Complaint.

86. BD denies the allegations contained in paragraph 86 of the Complaint.

**COUNT SEVEN
FRAUDULENT CONCEALMENT**

87. BD incorporates its responses to the allegations contained in paragraphs 1 through 86 of the Complaint as if fully set forth herein.

88. BD denies the allegations contained in paragraph 88 of the Complaint.

89. BD denies the allegations contained in paragraph 89 of the Complaint.

90. BD denies the allegations contained in paragraph 90 of the Complaint.

91. BD denies the allegations contained in paragraph 91 of the Complaint.

92. BD denies the allegations contained in paragraph 92 of the Complaint.

93. BD denies the allegations contained in paragraph 93 of the Complaint.

**COUNT EIGHT
LOSS OF CONSORTIUM**

94. BD incorporates its responses to the allegations contained in paragraphs 1 through 93 of the Complaint as if fully set forth herein.

95. BD is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second unnumbered paragraph of Count Eight of the Complaint, and therefore, can neither admit nor deny said allegations.

96. BD denies the allegations contained in the third unnumbered paragraph of Count Eight of the Complaint.

BD denies each and every allegation of the Complaint not otherwise specifically responded to in this Answer including, but not limited to, each and every allegation or claim for relief set forth in any prayer for relief asserted by Plaintiffs.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Plaintiffs have failed to state any claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are preempted, in whole or in part, by the Supremacy Clause of the Constitution of the United States of America and by the Medical Device Amendments of 1976 to the Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et. seq.*

THIRD AFFIRMATIVE DEFENSE

The injuries alleged by Plaintiffs herein are due to an assumption of the risk on the part of the Plaintiffs, thereby barring Plaintiffs from recovery.

FOURTH AFFIRMATIVE DEFENSE

The injuries and damages alleged by Plaintiffs herein were due to the contributory and/or comparative negligence of Plaintiffs, thereby barring Plaintiffs from recovery.

FIFTH AFFIRMATIVE DEFENSE

Any injuries, losses and damages sustained by Plaintiffs were caused, if at all, by the acts or failure to act of others over whom BD had no control.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for damages are barred in whole or in part by their failure to mitigate their damages.

SEVENTH AFFIRMATIVE DEFENSE

BD owed Plaintiffs no duty to warn because Plaintiffs were sophisticated users of latex products.

EIGHTH AFFIRMATIVE DEFENSE

BD owed Plaintiffs no duty to warn because the facilities at which either or both of them worked, and which provided either or both of them with latex products were sophisticated users and purchasers of such products.

NINTH AFFIRMATIVE DEFENSE

If Plaintiffs incurred any injuries, such injuries were the result of sensitivities, medical conditions, idiosyncrasies and/or allergic reactions peculiar to Plaintiffs and not found in the general public, which were unknown, unknowable or not reasonably foreseeable to Defendant BD and for which BD cannot be held responsible.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statues of limitation and repose, and, if so, should be dismissed.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrines of laches, waiver and/or estoppel.

TWELFTH AFFIRMATIVE DEFENSE

Any latex containing products designed, manufactured, sold and distributed by BD complied with all applicable industry and governmental standards and regulations and reflected the current state of the art at the time they were manufactured.

THIRTEENTH AFFIRMATIVE DEFENSE

The products of which Plaintiffs complain have certain unavoidable, inherent characteristics which cannot be obviated under the state of scientific knowledge existing at the time such products were manufactured. If Plaintiffs have sustained any injuries as a result of their use of or exposure to the products at issue, those injuries were the result of properties necessarily associated with the products that were unavoidable and for which BD cannot be held responsible.

FOURTEENTH AFFIRMATIVE DEFENSE

The products of which Plaintiffs complain have certain unavoidable, inherent characteristics. While denying that such characteristics are dangerous or defective, under the state of scientific knowledge at the time such products were manufactured, a practical and technically feasible alternative design that would have prevented the alleged harm was not available without substantially impairing the usefulness or intended purpose of the product. Consequently, BD did not act unreasonably in introducing the product into trade or commerce.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to state facts sufficient to sustain a recovery of costs and disbursements of this litigation.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs misused the products described, knowing that such misuse was unforeseen and unforeseeable to BD, with full knowledge of any danger resulting from misuse. Such actions legally caused and contributed to the injuries and damages, if any, Plaintiffs claim.

SEVENTEENTH AFFIRMATIVE DEFENSE

The injuries complained of by plaintiffs were not proximately caused by the use of any of BD's products as recommended or by any acts or omissions on the part of BD.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to join parties in whose absence complete relief cannot be afforded.

NINETEENTH AFFIRMATIVE DEFENSE

If Plaintiffs sustained the injuries alleged in the Complaint, which is denied, there was an intervening, superseding cause or causes leading to these alleged injuries; and therefore, any action on the part of BD was not the proximate and/or competent producing cause of the alleged injuries.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' exposure, if any, to products for which BD may be legally responsible was *de minimis*, so that BD's product(s), if any, were not a substantial contributing factor to any condition for which Plaintiffs seek recovery in this action.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The granting of relief requested by Plaintiffs would be unconstitutional under the New York and United States Constitutions in that it would violate due process and equal protection

guarantees, place an undue burden on interstate commerce, and violate the constitutional proscriptions against excessive fines.

TWENTY-SECOND AFFIRMATIVE DEFENSE

If BD is not identified as the manufacturer of the alleged injury-causing product, any recovery against BD would violate its rights under the Constitutions of the United States and New York, including, but not limited to, its rights to due process and equal protection under the Fifth and Fourteenth Amendments to the Constitution of the United States and Article I, Sections 6 and 11 of the New York Constitution.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs have failed to plead fraud or related claims of fraudulent concealment with sufficient particularity as required by the applicable pleading rules.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

BD hereby adopts and incorporates by reference, as if set forth fully herein, any affirmative defenses listed by any other Defendant in their Answer to Plaintiffs' Complaint to the extent that they are not factually inconsistent with BD's position.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

BD reserves the right to assert any additional affirmative defenses and claims of avoidance as may be appropriate based upon facts or issues disclosed during the course of additional investigation and discovery.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

This Court lacks jurisdiction over Defendant BD in that Plaintiffs failed to properly effect valid service of the pleadings on Defendant BD and failed to commence the action.

WHEREFORE, having fully answered Plaintiffs' Complaint, Defendant BD requests that the Complaint herein be dismissed in its entirety, with prejudice, that judgment be entered in favor of Becton, Dickinson and Company against Plaintiffs, that any and all claims for damages of any sort or nature be denied, and that Maxxim Medical, Inc. be awarded costs, attorneys' fees, and all other relief as is just and proper.

JURY DEMAND

BD hereby demands a trial by jury as to all issues so triable.

Dated: New York, New York
August 9, 2002

PIPER RUDNICK LLP

By: _____
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